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Dated: August 31, 2004.

Signature:

Lynn L. Janulis
(Lynn L. Janulis)



Docket No.: 01017/39555
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Mehta *et al.*

Application No.: 10/694,579

Art Unit: 1614

Filed: October 27, 2003

Examiner: Not Yet Assigned

For: G-CSF THERAPY AS AN ADJUNCT TO
REPERFUSION THERAPY IN THE
TREATMENT OF ACUTE MYOCARDIAL
INFARCTION

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 1.56, the attention of the United States Patent and Trademark Office is hereby directed to the references listed on the attached Form PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

The Applicants request that the documents listed on the attached Form PTO/SB/08 be made of official record in the above-identified application and considered by the Examiner. Copies of all listed documents cited on Form PTO/SB/08 are submitted herewith, with the exception of the U.S. Patent Documents, A1-A13, in accordance with the waiver of the requirement under 37 CFR 1.98 (a)(2)(i). While the information and references disclosed in this Information Disclosure Statement may be "material" pursuant to 37 C.F.R. § 1.56, it is not intended to constitute an admission that any patent, publication or other information referred to therein constitutes prior art under 35 U.S.C. §§ 102 or 103.

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. § 1.56(a) exists. It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98.

No fee is believed to be due under 37 C.F.R. §1.97(b) because this statement and Form PTO/SB/08 are being submitted before receipt of a first Office action on the merits in the above-identified patent application. Should the Patent Office determine that a fee is due for consideration of this Information Disclosure Statement, however, the Patent Office is hereby authorized to charge that fee to Deposit Account 13-2855. A copy of this paper is enclosed.

Dated: August 31, 2004

Respectfully submitted,

By 

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PTO/SB/08A (10-01)

Approved for use through 10/31/2002, OMB 0651-0031

U. S. Patent and Trademark Office: U. S. DEPARTMENT OF COMMERCE

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<p>Substitute for form 1449A/PTO</p> <h2 style="text-align: center;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="text-align: center;"><i>(use as many sheets as necessary)</i></p>				<i>Complete if Known</i>	
				Application Number	10/694,579
				Filing Date	October 27, 2003
				First Named Inventor	Mehta et al.
				Art Unit	1614
Examiner Name	To be determined				
Sheet	1	of	3	Attorney Docket Number	01017/39555

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
A1		4,810,643	03-07-1989	Souza	
A2		4,904,584	02-27-1990	Shaw	
A3		5,104,651	04-14-1992	Boone et al.	
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A9		5,824,784	10-20-1998	Kinstler et al.	
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A13		2003/0064922	04-03-2003	Nissen et al.	

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Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)			
B1		AU-A-76380/91	11-14-1991	Boehringer Mannheim GmbH	
B2		AU-A-10948/92	08-27-1992	Boehringer Mannheim GmbH	
B3		EP 0 243153	10-28-1987	Immunex Corporation	
B4		EP 0 256843	02-24-1988	Cetus Corporation	
B5		EP 0 272703	06-29-1988	Kyowa Hakko Kogyo Co., Ltd.	
B6		EP 0 335423	10-04-1989	Kyowa Hakko Kogyo Co., Ltd.	
B7		EP 0 370205	05-30-1990	Kyowa Hakko Kogyo Co., Ltd.	
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B9		EP 0 456200	11-13-1991	Boehringer Mannheim GmbH	
B10		EP 0 459630	12-04-1991	Imperial Chemical Industries PLC	
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B12		JP 04164098	06-09-1992	Kirin Amgen Inc.	
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B16		WO 90/12874	11-01-1990	Genetics Institute, Inc.	
B17		WO 91/05798	05-02-1991	Amgen Inc.	
B18		WO 91/11520	08-08-1991	Max-Planck-Gesellschaft	
B19		WO 91/18911	12-12-1991	Genzyme Corporation	
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B25	WO 95/21629	08-17-1995	Amgen Inc.		
B26	WO 96/11953	04-25-1996	Amgen Inc.		
B27	WO 01/51510	07-19-2001	Maxygen APS		
B28	WO 03/006501	01-23-2003	Maxygen APS		
B29	WO 03/030821	04-17-2003	Human Genome Sciences, Inc.		

Examiner Signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant

¹Applicant's unique citation designation number (optional). ²See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	C1	COLQUHOUN et al., Reversal of neutropenia with granulocyte colony-stimulating factor without precipitating liver allograft rejection, <i>Transplantation</i> 56:755-758, 1993.
	C2	DIFLO et al., Simultaneous use of ganciclovir and granulocyte colony stimulating factor in liver transplant recipients, <i>Hepatology</i> 16:PA278A, 1992.
	C3	FERRARI, et al., Muscle regeneration by bone marrow-derived myogenic progenitors, <i>Science</i> 279:1528-1530, 1998.
	C4	FUKUNAGA et al., Growth and differentiation signals mediated by different regions in the cytoplasmic domain of granulocyte colony-stimulating factor receptor, <i>Cell</i> 74:1079-1087, 1993.
	C5	GABRILOVE, Introduction and overview of hematopoietic growth factors, <i>Semin. Hematol.</i> 26:2 (Suppl 2):1-4, 1989.
	C6	GÖRGEN et al., Granulocyte colony-stimulating factor treatment protects rodents against lipopolysaccharide-induced toxicity via suppression of systemic tumor necrosis factor- α , <i>J. Immunol.</i> 149:918-924, 1992.
	C7	JACKSON et al., Regeneration of ischemic cardiac muscle and vascular endothelium by adult stem cells, <i>J. Clin. Invest.</i> 107:1395-1402, 2001.
	C8	JONES et al., Growth factors in haemopoiesis, <i>Bailliere's Clin. Hematol.</i> 2:83-111, 1989.
	C9	KOCHER et al., Neovascularization of ischemic myocardium by human bone-marrow-derived angioblasts prevents cardiomyocyte apoptosis, reduces remodeling and improves cardiac function, <i>Nature Med.</i> 7:430-436, 2001.
	C10	KUGA et al., Mutagenesis of human granulocyte colony stimulating factor, <i>Biochem. Biophys. Res. Comm.</i> 159:103-111, 1989.
	C11	LACHAUX et al., Treatment with lenograstim (glycosylated recombinant human granulocyte colony-stimulating factor) and orthotopic liver transplantation for glycogen storage disease type Ib, <i>J. Ped.</i> 123:1005-1008, 1993.
	C12	LANGE et al., Reperfusion therapy in acute myocardial infarction, <i>N. Engl. J. Med.</i> 346:954-955, 2002.
	C13	LU et al., Disulfide and secondary structures of recombinant human granulocyte colony stimulating factor, <i>Arch. Biochem. Biophys.</i> 268:81-92, 1989.
	C14	MOORE et al., Synergy of interleukin 1 and granulocyte colony-stimulating factor: <i>In vivo</i> stimulation of stem-cell recovery and hematopoietic regeneration following 5-fluorouracil treatment of mice, <i>Proc. Natl. Acad. Sci. USA</i> 84:7134-7138, 1987.

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C15	ORLIC et al., Bone marrow cells regenerate infarcted myocardium, <i>Nature (London)</i> 410:701-705, 2001.	
C16	ORLIC et al., Mobilized bone marrow cells repair the infarcted heart, improving function and survival, <i>Proc. Natl. Acad. Sci USA</i> 98:10344-10347, 2001.	
C17	ORLIC et al., Adult bone marrow stem cells regenerate myocardium in ischemic heart disease, <i>Ann. N.Y. Acad. Sci.</i> 996:152-157, 2003.	
C18	ROSENTHAL et al., Bone marrow-derived angioblasts may be used to promote cardiac revascularization in the days following a myocardial infarction, <i>Nature Medicine</i> 7:412-413, 2001.	
C19	SOUZA et al., Recombinant human granulocyte colony-stimulating factor: Effects on normal and leukemic myeloid cells, <i>Science</i> 232:61-65, 1986.	
C20	TAKANO et al., Pleiotropic effects of cytokines on acute myocardial infarction: G-CSF as a novel therapy for acute myocardial infarction, <i>Curr. Pharm. Des.</i> 9:1121-1127, 2003.	
C21	WELTE et al., Purification and biochemical characterization of human pluripotent hematopoietic colony-stimulating factor, <i>Proc. Natl. Acad. Sci. USA</i> 82:1526-1530, 1985.	
C22	WRIGHT et al., Granulocyte colony-stimulating factor (GCSF) combined with a interferon (α IFN) for treatment of liver allograft recipients with viral hepatitis, <i>Hepatology</i> 14:PA48, 1991.	

Examiner Signature		Date Considered	
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